

REMARKS

Claims 1-34 are pending in the application. Claims 7-9, 12-20, and 22-30 are withdrawn. Claims 1-2, 5, 10-11, and 21 have been amended. Claims 31-34 have been added. Support for the new claims and amendments may be found throughout the specification as filed. No new matter has been added.

Amendment of the claims should in no way be construed as acquiescence to any of the Examiner's rejections. The amendments to claims are being made solely to expedite prosecution of the present application and do not, and are not intended to, narrow the claims in any way. Applicants reserve the right to further prosecute the original or similar claims in the instant application, or in a divisional or continuation patent application.

Claim Objections

Claim 21 is objected to as being dependent on a non-elected claim. Claim 21 has been amended to omit reference to non-elected claims. Reconsideration is respectfully requested.

Rejection of claims 1-6, 10-11, and 21 under 35 U.S.C. § 112, second paragraph

Claim 1 stands rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite for reciting the term "SM22a." Applicants respectfully traverse; however, Applicants' amendments to claim 1 deleting the term "SM22a" render this rejection moot.

Claim 1 stands further rejected under 35 U.S.C. § 112, second paragraph as allegedly being vague for the recitation of "the differentiation of vascular smooth muscle cells comprising culturing neural crest cells." Applicants have amended the claim to recite "the differentiation of neural crest cells into vascular smooth muscle cells comprising culturing neural crest cells. . . ." Applicants believe that the amendment obviates this rejection.

Claim 1 stands further rejected under 35 U.S.C. § 112, second paragraph as allegedly being incomplete for omitting the active steps and conditions required to induce expression of SM22a. Applicants believe that the amendment to claim 1 obviates the rejection of this claim.

Claim 2 stands further rejected under 35 U.S.C. § 112, second paragraph as allegedly being vague and indefinite for the recitation of "immortalized cells." The Examiner alleges that it is unclear whether, "this is an active step required for the method, for which the steps are

omitted, or if this is indicating the starting materials to be a neural crest cell line.” (*See Office Action at p. 4.*) Applicants believe that the amendment to claim 1, from which claim 2 depends, obviates the rejection of this claim.

Claims 1 and 10 stand rejected under 35 U.S.C. § 112, second paragraph for allegedly omitting essential structural cooperative relationship between elements of vascular smooth muscle cells and neural crest cells. Applicants believe that the amendments to claims 1 and 10 obviate the rejection of these claims.

Claim 3 stands rejected under 35 U.S.C. § 112, second paragraph as allegedly being vague and indefinite for the recitation of “smooth muscle cell differentiation medium.” Applicants respectfully traverse. The specification states at page 50, lines 16-20:

Smooth muscle cell differentiation was induced by application of the media components listed in Table 1 supplemented with 10% fetal bovine serum, penicillin (100 units/ml), streptomycin (100 µg/ml), and 25 mM Hepes (pH 7.4), hereafter referred to as smooth muscle cell differentiation medium (SMDM).

Thus, meaning of the term “smooth muscle cell differentiation medium” is clear when read in light of the specification.

Claim 5 stands rejected under 35 U.S.C. § 112, second paragraph as allegedly being incomplete. The Examiner alleges that the “steps required to perform the culturing of cells in complete medium and the order in which the steps are to be performed.” (*See Office Action at p.4.*) Applicants believe that the amendment to claim 5 obviates this rejection.

Claim 6 stands rejected under 35 U.S.C. § 112, second paragraph as allegedly being vague and indefinite for the recitation of “chick embryo extract.” Applicants respectfully traverse. The specification states at page 50, lines 9-12:

Monc-1 cells were cultured in the undifferentiated state on fibronectin-coated plates in an L-15 CO₂-based medium supplemented with chick embryo extract, hereafter referred to as complete medium, as described by Stemple and Anderson (Stemple and Anderson, (1992) Cell 71, 973-985).

Thus, the specification thus clearly defines what is meant by “an L-15 CO₂-based medium supplemented with chick embryo extract.” Therefore, Applicants believe that the scope of claim 6 is clear and definite.

Claim 10 stands rejected under 35 U.S.C. § 112, second paragraph as allegedly being vague and indefinite for the recitation of a method of identifying “an agent that modulates which regulates proliferation or migration” The Examiner also alleges that claim 10 is missing a final step. Applicants believe that the amendment to claim 10 obviates this rejection.

Claim 11 stands rejected under 35 U.S.C. § 112, second paragraph as allegedly being vague and indefinite for the recitation of detecting the “presence or absence” as an indication of the ability of the agent to inhibit differentiation. Applicants believe that the amendment to claim 11 obviates this rejection.

Claim 21 stands rejected under 35 U.S.C. § 112, second paragraph as allegedly being incomplete for omitting essential steps. Applicants believe that the amendments to claims 10 and 21 obviate this rejection.

Claim 4 stands rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite for depending from an indefinite claim. Applicants respectfully traverse this rejection for the reasons set forth above for claim 3.

Accordingly, Applicants respectfully request that the Examiner withdraw the claim rejections based on 35 U.S.C. § 112².

Rejections of claims 1-6, 10-11, and 21 under 35 U.S.C. §102(e)

The Examiner has rejected claims 1-6, 10-11, and 21 under 35 U.S.C. §102(e) as being anticipated by Anderson et al. (U.S. Patent No. 5,672,499). More specifically, the Examiner states:

The Anderson et al. reference teaches an immortalized neural crest cell line and “methods for assaying the effects of various substances on neural stem cells. Such effects include the differentiation of said cells into neurons, glia, or smooth muscle cells. (*See Office Action at p. 6.*)

Applicants respectfully traverse the rejection. To anticipate a claim, a reference must teach each and every element of the claim. (*See MPEP §2131.*) Applicants respectfully submit that Anderson et al. do not teach the uniform differentiation of neural crest cells into smooth muscle cells. Thus, Anderson et al. do not teach culturing neural crest cells under conditions sufficient for the neural crest cells to differentiate uniformly into smooth muscle cells, as stated in Applicants’ claims. Rather, Applicants have obtained populations of smooth muscle cells in

which nearly 100% of the cells are smooth muscle cells. (See, e.g., specification at page 15, line 4.) Importantly, because each and every limitation of the rejected claims is not taught by the cited reference, the cited reference does not anticipate those claims.

Additionally, a reference anticipates a claimed invention only if the reference describes the claimed invention in sufficient detail to enable a person of ordinary skill in the art to carry out the claimed invention. (See *MPEP* §2121.) Anderson et al. do not teach conditions sufficient for the neural crest cells to differentiate uniformly into smooth muscle cells. Therefore, Anderson et al. do not describe the claimed invention in sufficient detail to enable a person of ordinary skill in the art to culture neural crest cells under conditions sufficient for the neural crest cells to differentiate uniformly into smooth muscle cells, as required by Applicants' claims. Anderson et al., therefore, do not anticipate the claims.

Accordingly, Applicants respectfully request that the Examiner withdraw the claim rejections based on 35 U.S.C. § 102(e).

CONCLUSION

Reconsideration is respectfully requested for the reasons set forth above. If a telephone conversation with Applicants' Agent would expedite the prosecution of the above-identified application, the Examiner is urged to call the undersigned at (617) 832-1000.

The Commissioner is hereby authorized to charge any necessary fees under small entity status to our **Deposit Order Account No. 06-1448, reference HUV-046.02.**

Respectfully submitted,

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